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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,073	12/15/2006	Vladimir Velebny	074047-00003 (KANIA-08)	8662

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EXAMINER	
BLAND, LAYLA D	

ART UNIT	PAPER NUMBER
1623	

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12/10/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,073	VELEBNY ET AL.	
	Examiner	Art Unit	
	LAYLA BLAND	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/21/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is a response to the declaration submitted August 28, 2008 and Applicant's amendment submitted August 28, 2008, wherein claim 1 is canceled, claims 2-10 are amended, and claim 11 is newly submitted.

In view of the cancellation of claim 1, all rejections made with respect to that claim in the previous office action are withdrawn.

In view of Applicant's amendment and remarks submitted August 28, 2008, the rejection of claims 1-10 under 35 USC 112, second paragraph is withdrawn. The claims now recite active method steps, "chewing substance" is deleted, and Applicant's remarks regarding "instant drink or syrup" are persuasive.

The following new rejections were necessitated by Applicant's amendment submitted August 28, 2008, wherein claims drawn to a method of manufacture are first presented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the manufacture of a preparation for the treatment of osteoporosis, does not reasonably provide enablement for the manufacture of a preparation for prevention of osteoporosis. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in Wands states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2sd 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method for manufacturing a preparation for the prevention and treatment of osteoporosis. No limiting definition of prevention is given in

the specification. In the absence of a limiting definition by the applicant, the ordinary definition of prevent, “to keep from happening or arising; make impossible," obtained from http://wordnet.princeton.edu, is applied. The claimed composition capable of preventing osteoporosis is therefore interpreted to one which is capable of eliminating the occurrence of osteoporosis.

(3) The state of the prior art and (4) the predictability or unpredictability of the art:

Stancikova et al. (International Journal of Tissue Reactions (2004), 26 (1/2), 9-16, abstract only) teach that oral administration of high molecular weight HA (0.75 MDa and 1.62 MDa) inhibits bone resorption and provides a protective effect on bone density in ovariectomized rats. The study only addressed the effects of HA on ovariectomy-induced bone loss in rats.

However, the risk factors for osteoporosis are many. MayoClinic.com teaches that risk factors for osteoporosis include sex, age, race, family history, frame size, tobacco use, lifetime exposure to estrogen, eating disorders, corticosteroid medications, thyroid hormone, SSRIs, other medications, breast cancer, low calcium intake, medical conditions and procedures that decrease calcium absorption, sedentary lifestyle, excess soda consumption, chronic alcoholism, and depression [pages 3-5]. The skilled artisan would have reason to doubt whether osteoporosis could be prevented, based on the many risk factors for the disease and the small and very specific patient population taught by Stancikova et al.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for the treatment of experimentally induced osteoporosis in ovarectomised female rats. The specification has not provided guidance for the prevention of osteoporosis in any subject or for the treatment of osteoporosis in subjects other than ovarectomised female rats.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the many risk factors for osteoporosis and the high unpredictability in the art as evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 (and all dependent claims) recites the limitation “using the composition in a dietetic preparation.” “Using” renders the claim indefinite because it is unclear which use is intended – a method of manufacturing or a method of treatment. For the purposes of examination, the claims are interpreted as a method of manufacturing, as is stated in the preamble of claim 11, and “for prevention and treatment of osteoporosis” is considered an intended use of the resulting preparation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 4, 7, 9, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Petito et al. (US 2003/0069171, April 10. 2003).

Petito et al. teach a nutritional composition containing sodium hyaluronate [see abstract]. The sodium hyaluronate should have a molecular weight range from about 50,000 to about 3,500,000 Daltons [0022]. Other agents such as vitamins can be added [0024-0025]. The nutritional compositions are formulated into powder, capsule, or tablet form for oral ingestion [0026]. Sodium hyaluronate should be present at about 1-15 mg/kg [claim 17]. It is noted that “for prevention and treatment of osteoporosis" does not further limit the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2 and 4-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petito et al. (US 2003/0069171, April 10, 2003) in view of Leneau (US 6,607,745, August 19, 2003), or as unpatentable over Leneau (US 6,607,745, August 19, 2003) in view of Petito et al. (US 2003/0069171, April 10, 2003).

Petito teaches nutritional compositions as set forth above, but does not teach compositions containing victuals or liquid compositions.

Leneau teaches a nutritional supplement containing hyaluronic acid or a salt thereof and a food carrier, wherein the amount of hyaluronic acid is from about 0.1 µg/kg to about 400 µg/kg of body weight [see abstract]. The HA or salt is formulated into a liquid aqueous concentration (considered a syrup) such as a dietary supplement formulation, which is diluted in portions and mixed with food, water, or other beverages [column 2, lines 59-67]. Otherwise the HA or salt can be packaged in individual solid or liquid doses such as capsules or gel seals and the concentrate mixed with a beverage [column 3, lines 1-7]. Leneau teaches that the molecular weight of HA ranges from 50000 to about $8X10^6$ Daltons, which encompasses but does not anticipate the range recited in claim 11.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate Petito's nutritional compositions into the food and beverage formulations taught by Leneau. Petito's formulations are described as "nutritional," so it flows logically to incorporate them into foods and beverages as taught by Leneau. Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use sodium hyaluronate having molecular weight from

about 50,000 to about 3,500,000 Daltons in the compositions taught by Leneau et al., because Petito teaches that this is an appropriate molecular weight range for orally administered hyaluronic acid. Although Leneau does not explicitly teach victuals such as coconut flour, these are considered obvious in view of Leneau's general teaching of food and beverages. Furthermore, although Leneau does not explicitly teach the preparation of a liquid form containing potassium sorbate as preservative, it is well known that potassium sorbate is used as a preservative in many foods and beverages, so it is obvious to prepare a liquid composition comprising potassium sorbate.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Petito et al. (US 2003/0069171, April 10, 2003) in view of Leneau (US 6,607,745, August 19, 2003), or vice versa, as applied to claims 2 and 4-11 above, and further in view of Takahashi et al. (US 6,232,301, May 15 2001).

Petito et al. and Leneau teach as set forth above, the preparation of oral formulations comprising hyaluronic acid or a salt thereof, specifically sodium hyaluronate. Petito et al. and Leneau do not explicitly mention the calcium salt of hyaluronic acid, but the skilled artisan would understand that calcium hyaluronate could be used in place of sodium hyaluronate because such salts of HA are commonly used.

For example, Takahashi et al. teach a pharmaceutical composition comprising hyaluronic acid or a salt thereof [see abstract], wherein sodium hyaluronate, potassium hyaluronate, and calcium hyaluronate are “usually used” [column 4, lines 39-44]. Thus,

it would have been obvious to use calcium hyaluronate in the formulation as discussed above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
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